Ministry of Health

MEDICAL OXYGEN PLANT PSA-TECHNOLOGY SPECIFICATION GUIDELINE

Medical Grade Oxygen Plant

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Foreword

Hypoxemia, below thenormal level of oxygen in tissue, is commonly associated with mortality in developing countries, yet feasible and cost-effective ways to address hypoxemia receive little attention in current global health strategy. The ability to detect and treat hypoxemia is critical for patient care and quality of services, especially for children and neonates. As a life-saving medicine, oxygen should be available at all hospitals and most health centers (HCs). Oxygen is vital to combat pneumonia-relatedunder-five children mortality and morbidity and for the treatment of many emergencies, including cardiac arrest, acute blood loss, shock, dyspnea (breathlessness), pulmonary edema, unconsciousness, convulsions (eclampsia), and fetal distress during labor. It is also included in the World Health Organization (WHO) list of essential medicines.

The FMOH in its five years Health Sector Transformation Plan (HSTP) prioritized improving equitable access to quality health services to all segments of the country. To realize this transformational agenda, the ministry devised multiple initiatives including Newborn and Child Survival Strategy, Maternal and Neonatal Health (MNH) road map, Saving Lives Through Safe Surgery (SaLTS) initiative, theestablishment of trauma centers, strengthening of emergency medical services and expansion of ICU services. All these initiatives and services require sustained and adequate availability of oxygen. Furthermore, there are also initiatives by the FMoH and RHBs to improve O_2 facilities including procurement and distribution of cylinders to health centers and more recently establishment of O_2 Plants in some referral hospitals.

Despite these efforts, the majority of health facilities, health centers, in particular, have limited availability and functionality of O_2 and pulse oximeter. Moreover, the current oxygen production is not adequate and Plant distribution is concentrated in few areas. Besides, the oxygen demand will continue to increase significantly over next five years with more facilities to be built and starting providing service. Additionally, demand for on-site oxygen generation solutions continues to rise across a number of facilities. Based on recent

quantification exercise, at current occupancy, Ethiopia would need 234,000 M^3 per month (~1240 cylinders/day) by end of 2017 to fulfill its oxygen requirement with nearly 10% being driven by child/neonatal consumption to fulfill its oxygen requirement by Fiscal Year

Cognizant of these challenges and demands,the Federal Ministry of Health (FMOH) has developed and launched a national medical oxygen and pulse oximeter scale up road map which provides guidance, and support to all relevant authorities, in order to increase manufacturing capacity at national level.

According to the roadmap, oxygen Plants for medical gas need to be built in 13 selected referral and university hospitals with a centrally planned and guided procurement process to ensure high-quality and sustainable equipment. To realize these efforts and avail quality and sustainability of equipment a standard procurement and specification guideline is avital step.

Hence,the FMoH has developed this specification guidelineto standardized oxygen Plantsspecification which will be procured and installed from now onwards in Ethiopia public hospitals.

Therefore, the FMoH urges all care providers and implementing partners to refer this specification guideline in order to procure/institute quality and standard equipment.

Name and Title

The Federal Democratic Republic of Ethiopia

The Scope of the Document and How to use it

In the absence of an internationally accepted standard for Pressure Swing Adsorption (PSA) oxygen Plants, this document can be used as a tool by which to help standardize proposed Plants, for assurance of component completeness, and/or for tender guidance and/or evaluation. In its current state:

- *This is not a tender document*
- *This is not a contract document*

Use of this document for tender or contract documents will require revisions and modifications by owner. All variables requiring input have been highlighted in yellow.

There are components of this document that might not apply across all cases, and therefore can be removed (e.g. decisions might be taken to not install distribution manifolds and using cylinders directly in the ward might be the choice taken). This document also includes components that go beyond Plant procurement (e.g., structural requirements of the host facility).

Furthermore, in terms of language, "should/shall" is to be interpreted as a recommendation, whereas "must" is to be interpreted as a mandatory requirement.

<u>Sizing and design for all Plants should take into consideration the following points:</u>

- Needs assessment / determining O_2 demand

When conducting a needs assessment for sizing a Plant, a comprehensive review of historical medical data is to be conducted and current oxygen demands must be evaluated and quantified, allowances should be made for an increase in the use of O_2/changes to the gas demands caused by local developments and strategic issues. A review of similar sites with existing Plants should also be made. It should be noted that higher consumption could be expected when for

examplehigh numbers (>20) of CPAP machines are in frequent use (>40 hours/week). Future plans and/or expected growth shall be taken into consideration.

In addition, mapping of nearby facilities or of the referral catchment of the hospital can also give an indication of additional needs should the facility consider the sale and distribution of oxygen cylinders outside of the facility.

An example to assess and determine the demand of oxygen Plant capacity

Determine oxygen consumption for your respective health facility.

Assume Adama hospital has the following number of beds, hypoxemia prevalence bed turnover ratio, oxygen consumption per case; number of beds per ward medical 50, surgical 40, Gyn/obs40, pediatrics and NICU 40, OR and Recovery 4, ICU and Emergency 20, prevalence of hypoxemia 20% bed turnover ratio 8in a quarterand oxygen consumption per case 4000 liter.

A. *Calculate oxygen consumption for each ward*
B. *Total oxygen consumption of the hospital*

Answer

A. *Oxygen consumption for each ward*
    1. *Medical 50*0.2*8 = 80 cases of hypoxemia * 4000 lit =320, 000 lit*
    2. *Surgical ward 40*0.2*8 = 64 cases of hypoxemia * 4000 lit =256000 lit*
    3. *Gyn/Obs ward 40*0.2*8 = 64 cases of hypoxemia * 4000 lit =256000 lit*
    4. *Pedi & NICU ward 40*0.2*8= 64 cases of hypoxemia * 4000 lit =256000 lit*
    5. *OR & Recovery 4*0.2*8= 6.4 cases of hypoxemia * 4000 lit =25600 lit*
    6. *Emergency unit 20*0.2*8= 32 cases of hypoxemia * 4000 lit =128000 lit*

B. Total oxygen consumption of the hospital is = *1,241,600 lit/quarter*

NB. Similar exercise should be done to calculate the catchment area oxygen consumption

This document can be used irrespective of Plant size. All adjustments to be made in the document have been ***bolded in italic*** and can only be done so after needs assessment has been carried out. This document does not determine Plant size needed.

Plant components come either skid-mounted or containerized for assurance of completeness, to help with transportation, and to help with final installation.

- Emergency preparedness/back-up supply

Both BS EN 737-3:2000 and ISO 7396-1:2016 propose that all medical gas supplies should comprise three sources of supply identified as "primary", "secondary" and "reserve". Considerations should be made to Plant& distribution/manifold, on-site concentrators, on-site cylinders as well as power needs and back-ups (where needed) to ensure a continuous supply.

Another design consideration to be made would be to have two Plants in parallel with a total production capacity to meet (or slightly) exceed needs. This case would allow for downtime/maintenance on one of the Plants, whether planned for or unforeseen.

Operational Policy Document

The owner should consider developing an overarching operational policy document, which should include, but not be limited to:

- All engineering documents relating to the oxygen Plant and distribution (drawings, specifications, etc.).
- Standard operations guidelines: user and maintenance manuals, including all details and schedules of necessary works.
- Safety & security in working with and managing oxygen, a non-flammable gas that strongly supports combustion.
- Detailed instructions relating to the use of emergency reserve or backup oxygen supply (resulting from power supply interruption, drop in quality, etc.) for assurance of continuity of supply, including details of capacity.

- Planned preventative maintenance schedules.
- All troubleshooting documents that address indications or faults contained herein.
- Procedures and templates for filing and retaining all maintenance and testing documents.

Decisions need to be taken in order to determine specific needs, all of which need to be customized in this document and have been left ***italics and bolded*** for completion.

Acknowledgments

The Federal Democratic Republic of Ethiopia Ministry of Health would like to acknowledge and thank the various individuals and organizations who contributed their knowledge, expertise and time to develop and review this sample specification which will provide practical guidance for developing aspecification in aspecific context and standardize future procurement of oxygen Plants in Ethiopia. We are grateful to the following individuals for their contribution to the development of this sample oxygen Plant specification.

List of Participants

Table 1 List of Participants and organization represented

S.No	Name	Organization
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Acronyms

Some acronyms listed below are units and/or industry terms that are not necessarily spelled out in the document but have been defined for improved understanding by non-technical reviewers. Furthermore, some refer directly to international standards, which have been defined in this list, but more details can be found in Annex 1 – Standards Referenced.

ASME	American Society of Mechanical Engineers
ASTM	American Society for Testing and Materials
AVSU	Area valve service units
Bar	1 bar = 100 kPa (unit of pressure)
BS	British Standard (though not SI, integral in certain aspects
CE	European Conformity (from French ConformitéEuropéene)
CPU	Central processing unit
DC	Direct current
ELV	Extra-low voltage
ERM	Emergency reserve manifold
FAT	Factory acceptance test
Hz	Hertz (unit of frequency)
ICU	Intensive care unit
ISO	International Organization for Standardization
Kg	kilogram (unit of mass)
kPa	kilopascal (unit of pressure)
mA	milliamp (unit of electric current)
NIST	Non-interchangeable screw thread
O_2	Oxygen
PDP	Pressure dew point
PPM	Planned preventative maintenance
PSA	Pressure swing adsorption
PTFE	Polytetrafluoroethylene – a synthetic fluoropolymer (also known as Teflon ®)
SI	International System of Units (metric units)
V	volt (unit for electric potential)

Introduction

As a life-saving medicine, oxygen should be available in all hospitals and health centers (HCs). Oxygen is vital to reduce mortality and morbidity from cardiac arrest, acute blood loss, shock, dyspnea (breathlessness), pulmonary edema, pneumonia, unconsciousness, convulsions (eclampsia), and fetal distress during labor.

Currently, Oxygen availability varied widely across regions, and between facility types (hospitals Vs health centers) in Ethiopia. Oxygen availability was generally higher at the hospital level.

From the recent assessment in December, 2016, only 3% of health centers and 26% of hospitals have regular practice of oxygen consumption and stock monitoring mechanism, while 9% of health centers and 47% of hospitals think there are enough refilling sources for oxygen, which shows a need to expand supply base for oxygen supply both for health centers and hospitals. Having an appropriate supply monitoring practice and timely refilling system is also critical at the facility level.

Except 3 hospitals already functioning, and a few others under construction, there is no public oxygen refiling center. The few private medical & non-medical oxygen suppliers are located in Addis Ababa, in which accessibility is one of the critical challenges so far observed; some health facilities are supposed to travel more than 800km for refilling.

Moreover, the current oxygen production is not adequate and Plant distribution is concentrated in few areas. Furthermore, the oxygen demand will continue to increase significantly over next five years with more facilities to be built and starting providing service.

Additionally, demand for on-site oxygen generation solutions continues to rise across a number of facilities. Based on recent quantification exercise, at current occupancy, Ethiopia would need 234 K M3 per month (~1240 cylinders/day) by end of 2017 to fulfill its oxygen requirement with nearly 10% being driven by child/neonatal consumption while it might need close to 1 B liters per month (equivalent of ~4,700 large cylinders/day) to fulfill its oxygen requirement by Fiscal Year

(FY) 2020/21 with expected infrastructure expansion driven by primary hospitals as well as improved health service utilization.

Recognizing this, the Federal Ministry of Health (FMOH) has developed and launched a national medical oxygen and pulse oximeter road map which provides guidance, and support to all relevant authorities, in order to increase manufacturing capacity at national level.

According to the road map, oxygen Plants for medical gas need to be built in 13 selected referral and university hospitals with a centrally planned and guided procurement process to ensure high-quality and sustainable equipment. These hospitals will use oxygen for their own consumption, as well as refill nearby health centers and hospitals with cylinders, or could also sell to private facilities.

Therefore, this specification is prepared to standardized oxygen Plants which will be procured and installed from now onwards in Ethiopia public hospitals.

Description of Function

Oxygen Plantconsists of Air compressor with 7.5 bar output pressure, pre-filters, Refrigerator Air dryer, fine filters, carbon activator filter, Air receiver tanker which 3000 litters, oxygen generator with purity 93±3% and total output 90-120m3/hr. regulators, valves, control systems, alarms, high-pressure booster which is a method of boosting oxygen from Oxygen Tanker to filling station up to 200 Bar and with theinput of 7.5 Bar with flow rate 80m3/hr. (which assume that 2/3rdwill supply to other institution and 1/3rd for their own consumption). The booster can fill more than 214 type D cylinders in 16 working hours and can supply simultaneously 1/3rd of the production to the piping system.

Section 1: Scope of Technical Specifications

The Plant under consideration must be able to offer an integrated medical grade oxygen production and distribution system as described in theses pacifications. Themake and/or model of the proposed system should have a proven track record in similar operating contexts.

The technical specifications for the functionality of the system are prime components for assurance of appropriate system design and selection;specifications are the operating guidelines as well as for compliance and certification purposes.Products under considerationmust comply with the minimum specifications as outlinedherein and listed in Annex 1 or justifiable equivalents. Plantsmay contain components of mixed national standards (e.g. components from both Europe and the USA), but compatibilitymust be verified.

Proposed alternate items/components will be considered so long as they also conform to the defined international standards mentioned herein and are deemed acceptable by the owner, though these must be clearly indicated.

All dimensions herein are of the International System of Units (SI units), also known as metric units. Products proposed and delivered must be functional and should have SI units.

Section 2: Plant Design and Layout

2.1 General

(To be completed based on site specifics, initial planning and needs assessment).

Overarching specifications of Pressure Swing Adsorption (PSA) oxygen Plant and requisite components:

Table 2 Overarching specifications of Pressure Swing Adsorption (PSA) oxygen Plant and requisite components

Component	Specification
Plant size:	• *90-120m^3/hr. (The size of the plant is determined by the need assessment of the specific plant)* • *Pressure swing adsorption technology*
Oxygen output quality	Purity of 93 ±3% *At elevation of up to 2,500 m above sea level*

	All requisite analyzers included.
Operating conditions	*10 –45°C* and <95% relative humidity
Power requirements	*380v±15%volts/50 Hz (3 phase)* *Capable of withstanding voltage fluctuations*
Compressors	*Feed air: maximum of 750 kPa/7.5 bar* *Oxygen boosting: 20,000 kPa/200 bar*
Distribution Manifold (Y/N)	*Size of primary manifold 10 each side (L & R)* *Size of emergency reserve manifold 5 per ward*
Supplemental filling ramp	*Size 10 cylinder each side (L & R)*
Cylinders	Total number # 500 of J - size
Pipeline requirements	Total length: *depend on the facilities' design* Total terminal units: *per No of Bed* Point of use pressure: 400 kPa/4 bar or 55psi
Mobility / installation-ready	Plant components skid-mounted or containerized
Units	All displayed units in SI (metric)

Specify whether works are to new ortoconducted on existing infrastructure. If the later, a section on thedegree of retrofitting will be required.

To note:

- Plant component sizes (air receiver tanks, PSA units etc.) will be based on decided Plant size, as determined by a needs assessment.

2.2 Siting

- The Plant should be located in a dedicated room (can be co-located with some other medical gases).
- The Plant should have all-round access for maintenance purposes; space allowance should be made for changing of major components.
- Air intake duct for compressor inlets must be located externally. They should not be installed as an alternative to the provision of adequate ventilation for cooling purposes.
- The Plant should be sited away from any potential fuel source, excess heat or spark.

2.3 Structural

2.3.1 Ventilation& Air Circulation/Conditioning

- The siting of the Plant should allow for adequate flows of air for three different purposes:
    a. Air intake to the compressors;
    b. Cooling of the compressed air by the aftercoolers;
    c. Cooling of the compressors; and,
    d. Cooling of controls
- Ventilation louvers should be provided at both high and low levels for allPlant and manifold rooms to allow circulation of air. Separated openings, equivalent to *at least* 1.5% of the total area of the walls and floor should be provided.
- All ventilation louversmust be vermin/birdproof.
- PSA Plants and compressors liberate, under maximum flow conditions, considerable heat. The ***ambient temperature of manifold rooms and Plantrooms should be maintained within the range of 10–45°C*** and below 95% relative humidity. If this is not possible, especially during operations, mechanical ventilation or air conditioning must be provided.
- A tropical thermostatic sensor should be installed in the Plant room.

2.3.2 Lighting

According to BS EN 60529:1992+A2:2013, by means of bulkhead light fittings:

- Plant rooms should be provided with a lighting level of 200 lux.
- Manifold rooms should be provided with lighting to an illumination level of 150 lux.

2.3.3 Noise Control

Plant rooms should be designed and constructed to ensure adequate control of noise emission.

- Size of the Plant will have a direct impact on noise levels. Consideration should be given to providing acoustic enclosures to reduce the free-field noise levels in noise-sensitive areas adjacent to Plant rooms so as not to exceed 80 dB.
- Acoustic enclosure and/or Plant room design must not inhibit normal cooling functions or maintenance activities.
- Discharge from some vacuum pumps may require silencing.
- Compressors and pumps should be affixed to an anti-vibration mounting, where necessary, to minimize transfer of noise and vibration to the structure of the building.
- All pipework and electrical conduits connected to the Plant should be fitted with flexible connectors where necessary to prevent the transmission of noise and vibration along the pipelines and conduits. Electrical bonding will be required.

2.3.4 Labelling/signage

Labelling and signs for medical gas systems, equipment and housing should be in accordance with the following:

Table 3Labelling and signs for medical gas system

Wording	Notes
Medical Gas Plant Room - No Unauthorized Entry	Adjacent to or on external door
Fire action	On door/wall External or internal
Oxygen services, use no oil	All gauges in oxygen circuit
Keep locked	On door(s)
Noise Hazard (+ ear defender symbol) Electric shock hazard Permit-to-work must be used	Adjacent to, or on, external door
Plant is connected to essential electricity supply	"E" symbols can be used on switches

	etc.
Danger 220 volts; Danger 380 volts	On Plant/switchgear
Danger rotating machines Warning: These machines stop and start automatically without warning Do not isolate without a Permit	Posted adjacent to Plant
Medical air intake "Do not obstruct"	On external intakes only
Danger medical gas exhaust *or* Danger explosive gases, no smoking, no naked lights	Posted on external wall by discharge pipes
Emergency Tel No Gas Supplier (if applicable) Pharmacy number Plant operator number	External wall
National Occupational Health and Safety Law	Internal wall
First aid	Internal wall

Cylinder recognition charts, indicating volume (liters of O_2) and weight (kg), supplied by the medical gas supplier, should be prominently displayed as appropriate.

Caution: Oxygen is a non-flammable gas, but strongly supports combustion! A clear safety and security plan is to be included in an operational policy document.

Section 3: Oxygen generation Plant

- The Plant is to deliver 93 ±3% medical-grade oxygen at European or US Pharmacopoeia monograph quality standards and at a pressure of 400 kPa (4 bar) for piped hospital oxygen systems or be available for additional compression to fill cylinders.

- Plant installation should be carried out only by specialist firms registered to BS EN ISO 9001:2000 and BS EN ISO 13485:2016 with the scope of registration appropriately defined.

3.1 Air Intake & Compression Unit

The air intake and compression unit, including the feed air compressor, dryer, filter bank and air receiver tank must be mounted on a welded steel skid or containerized.

3.1.1 Feed Air compressor

- The air compressor must be manufactured to internationally acceptable standards with CE mark and/or ISO 9001 certification.
- For added supply security, consideration should be given to duplex compressors if the original design is not two parallel Plants.
- Each compressor may require ducting to ensurean adequate flow of cool air. The operatingtemperature range indicated by the manufacturer should be considered during system design - refrigeration of the coolingair may need to be provided.
- Air compressor should be suitable for both continuous and frequent start/stop operations at a nominal outlet pressure of 750 kPa (7.5 bar) gauge. It can be of reciprocating multistage, positive displacement, piston type or oil lubricated rotary screw type.
- Supplied with all accessories for full installation and operation - flywheel, foundation bolts, motor pulley, v-belts, belt guard, and slide rails for the motor.
- Intake air temperature: 10 - 35°C
- Gross particle filters down to 1 micron to be placed on the inletside of the compressor.
- The compressor must be microprocessor controlled and programmable with the following minimum features:
    i. Automatic control of the operation of the compressor.
    ii. Compressor protection by shutting down the compressor or visible alarm lamps and audible alarm if any of the pre-set values are exceeded.

iii. Have a meter to monitor components and running hours ofservice.

iv. Provide automatic restart after voltage failure.

v. Emergency switch to shut down the Plant in case of emergency.

vi. The compressor will have anautomatic load-unload regulation system and automatic drain.

- The compressor must be silenced if needed as indicated in section 2.3.3 Noise Control.
- Compressed air output requirements:
  - Dry, oil-free and clean compressed air to prevent contaminants entering the oxygen generator equipment and to protect patients and instruments.
  - Volume: *Manufacturer rated to suit Plant output design*
- A multistage oil separator capable of achieving 2 ppm oil carry-over must be fitted to minimize contamination and maintenance.
- Completely enclosed fan-cooled electric motors must be used and incorporate maintenance-free greased for life bearings.

3.1.2 Dryer

- The compressed air dryer must be manufactured to internationally acceptable standards with CE mark and/or ISO 9001 certification.
- The dryer must be of continuous and fully automatic operation with no net air loss.
- Supplied with electronic control, communication and monitoring module for pressure regulation and monitoring in vessels.
- The dryer must be sized to dry 100% of the air compressor capacity with minimal power consumption.
- Equipped with safety valves.
- Either desiccant or refrigerant-type dryers are acceptable.
- Desiccant dryers are usually integrated within the molecular sieves and therefore do not regenerate independently. In this case, the pressure dew point (PDP) of the compressed air must not be above -35°C @ 10°C ambient.

- Refrigerant dryers should be of simple plug and play concept. The pressure must be self-regulating. The dryer must be able to reach 3°C PDP at 45°C and must include:
    - A refrigerant circuit
        - Refrigerant separator and compressor
        - Maximum pressure switch and fan control switch
        - Condenser fan and condenser
        - Capillary filter and tube
        - Hot gas bypass
    - An air circuit
        - Air inlet to refrigerant heat exchanger
        - Air/heat exchanger
        - Water separator
        - Automatic drain
        - Air outlet

3.1.3 Filters

- All air filters must be either dry medium filters or high-grade paper element filters of theinternationally acceptable brand name with the performance of each filter declared on a certificate issued by thereputable accredited laboratory to be in compliance with BS ISO 5011:2000.
- Air-inlet filters should be fitted either to the compressor inlet or at a suitable point in any ductwork before initial intake (as specified in feed air compressor section).
- A filterbank between compression and concentrationmust include:
    - High efficiency coalescing filtersmust be used to remove oil and dust particles.
    - An activated carbon filter must be included to absorb oil vapors providing clean air to ISO 8573-1:2010 class 1.
    - The filter bank assembly must include a solenoid-operated shut-off valve that is controlled in conjunction with the carbon monoxide monitor (see section 6).

- The filters must be High Efficient Coalescing filters to remove Moisture, Dust Particle up to 0.01 micron, Oil Aerosols up to 0.003mg/cu.mand bacteria Penetration up to 0.0001%.

- An additional sterile filter after concentrationmust be included post compression. This filter will also protect against zeolite dust particles from entering thefinal compressor.
- It must be reusable and suitable for steam sterilization in an autoclave.
- The filters must be replaced no less than 6 months of operation

3.1.4 Air receiver tank

- Air receivers must be designed and manufactured byAmerican Society of Mechanical Engineers(ASME)VIII code or Directive 97/23/ECor equivalent for pressure vessels.
- Pressure test certificates issued by an accredited laboratory must be provided.
- Volume: Manufacturer rated to suit Plant output design approximately ***2 x 3000L***
- Vertical floor mounted design equipped with pressure gauge, pressure regulator(transducer),safety release valve, manual and automatic, thezero-loss drain valve (float-type are not acceptable).
- The receiver assembly must be fitted with a pressure safety valve capable of passing the maximum flow output of the compressor at 10% receiver overpressure.
- The Air receiver tank must communicate and manageby the main control system.

3.2 PSA/Oxygen generator unit

- The productmust have proven performance in similar contexts, with climatic extremes and power reliability issues, preferably in Ethiopia 2 x PSA Oxygen Generator.
- Volume: ***90-120m^3/hr***. *(The size of the plant is determined by the need assessment of the specific plant)*
- The PSA generator unit, the booster compressor, the system tanks, the oxygen monitoring stand and the power control panel must be mounted on a welded steel skid or containerized.

- The components must be pre-piped, wired and tested before shipment with a test certificate issued by themanufacturer (see Section 8: Validation & Verification).
- PSA standard purity module supply/compressed air intake required, as per ISO 8573-1:2010 clause 1-4-1:

  a. Minimum supply pressure: 750 kPa (7.5 bar)
  b. Maximum Pressure dew point (PDP): -35 ˚C @ 10 °C ambient (if built-in desiccant type dryer)
  c. Oil-free: 100% filtration
  d. Minimum air intake: Atmospheric Air
- Minimum and maximum ambient operating temperatures: 10°C -45°C
- Required oxygen output according to ISO 8573-1:2010 clause 1-2-1, with purity of 93 ±3% at minimum of 4 bar and approximate PDP of -10°C maximum
- Capable of maintaining purity at elevation up to 2,500 m above sea level

- The Oxygen should be medical grade and mustbe producedwith purity of 93% ±3%.
- The Oxygen Concentrator system must have PSA sieve beds with Touchscreen for display of Real-Time trending, curves of Oxygen pressure, Display of Purity of Oxygen flow, alarm facilityfor process cycle failure, low oxygen pressure and for any other malfunction.
- The Oxygen concentrator should have Zirconium sensor with Oxygen Analyzer.
- Oxygen Concentrator module should be European Conformity (CE) marked, meeting ISO-10083 standards and Medical Device Directives 93/42/EC for Medical use
- The Oxygen Concentrator module must communicate and manage the main control system
- The Oxygen Concentrator module should have manual or automatic safety valve, drain valve,and low, high-pressure shutdown
- The Oxygen Concentrator module should have shut down or Auditory,visual alarm for low oxygen purity

3.2.1 PSA Vessels

- The two PSA Vessels must be designed and manufactured to ASME VIII code or Directive 97/23/EC or equivalent for pressure vessels.
- Pressure test certificates issued by an accredited laboratory must be provided.
- Certificates must be provided for each vessel attesting that the vessel, including valves, has been cleaned to aninternationally accepted procedure approved by American Society for Testing and Materials (ASTM) G93 or equivalent.

3.2.2 Molecular Sieve Units

- The Plant should comprise of duplexed air treatment/molecular sieve devices to permit continuous generation of oxygen: two sets of filters and a pair of molecular sieves. One of the sieves will be in the adsorbing stage, whilst the other regenerates.
- Each vessel will have adual gas baffle and strainer assemblies to protect and contain the molecular sieve.
- Each molecular sievemust be a high-performing chemically produced zeolite as the molecular sieve media that has been compacted to the correct density by means of vibration to adsorb specific types of molecules (such as water vapor or nitrogen).
- Pneumatic valves must control the generation and regeneration process to ensure proper changeover between the two sieve devices.

3.2.3 Oxygen receiver/buffer tank

- *2* 3000 Litter*
- The oxygen receiver tankmust be designed and manufactured to ASME VIII code or Directive 97/23/EC or equivalent for pressure vessels.
- Pressure test certificates issued by an accredited laboratory must be provided.
- Certificates must be provided for each vessel attesting that the vessel has been cleaned under aninternationally accepted procedure approved by ASTM G93 or equivalent.
- Vertical floor mounted design equipped with pressure gauge, safety release valves.

- Vertical floor mounted design equipped with pressure gauge, pressure regulator(transducer), safety release valve, manual and automatic, thezero-loss drain valve (float-type are not acceptable).
- The receiver assembly must be fitted with a pressure safety valve capable of passing the maximum flow output of the compressor at 10% receiver overpressure.
- The oxygen receiver tank must communicate and manage the main control system.

3.2.4 PSA Operations

- The unit must have aneasily accessible filter and valve strut assemblies that bolt directly to the vessel structure. The filter must be accessible and be able to be monitored without the removal of panels and doors (e.g. the solenoid is to include indicator lights).
- The flow controlling and metering valves must be adjustable and lockable. They must be colored and numerically coded to indicate theposition of locked down setting.
- The unit will contain an over-pressurization protection circuit that will vent compressed gas at a pre-set pressure. All gas components will be manufacturer rated to design requirements.
- The unit will have pressure gauges to indicate/regulate pressure at the inlet of each vessel and afinalproduct outlet. The gauges should be readable from the front of the unit without the removal of panels or doors.
- The unit must be supplied with anautomatic valve to vent to the atmosphere the initial gas produced at startup and during restarts to prevent contaminating the system with theoxygen of lower purity than required.
- The complete Plant must be able to automatically shut down when there is no demand for oxygen and automatically restart when there is demand for oxygen.

3.3 Oxygen booster compressor (oil-free)

- Air cooled, oil-less/non-lubricated, oxygen compatible multi-stage compressor with:
  - High and low-pressure automatic safety shutdowns;
  - Medium- and high-pressure relief valves; and

  - Pressure gauges to measure the inlet, first and second stage discharge pressures.
- Pressure filling range: 10,000 kPa – 20,000 kPa (100-200 bar) gauge cylinders.
- Designed to operate between *10°C to 45°C* ambient and up to 95% relative humidity
- Compressors must operate on an inlet pressure auto-cycling system (auto start/stop).
- Have meter to monitor running hours of operations.
- The compressor must safely process pure oxygen gas without oxidation or combustion.
- Power requirements:*380±15% V / 50 Hz / 3 phase*
- Suction pressure: approx. 7.5 bar
- High-pressure boosters should be compactly mounted on a Mild Steel frame fitted with electric motor
  - Output capacity of *80 m^3/hr*. (cubic meter/hr.)
- The High-pressure booster system should be provided with all interconnected piping from oxygen tanker and should have a system so as to connect easily with filling station or manifold.
- The compressor must be automatically coupling system, auto start/stop system
- The High-pressure booster must includeOil-less and non-lubricating compressor, motor, start/stop and emergency button, hour meter, high-pressure safety shutdown, safety relief valve, low inlet pressure shutdown, pressure gauge, drive belt, beltguard, oxygen clean and cooling fan
- The High-pressure booster must communicate and manage the main control system.
- The High-pressure booster must compatible with the oxygen Plant
- The high-pressure booster discharge/filling station/ neardistance tothe oxygen Plant
- The system should have pressure cut off valves to cut the supply from HPB as soon as the desired pressure of 150 bar is achieved.

3.3.1 Supplemental Cylinder Filling Manifold

- A high pressure filling ramp, tested up to 30,000 kPa (300 bar) gauge (complete with test certificate), must be available for on-site cylinder filling
- Cylinder filling manifold: To hold *(number) x (size "J" or "H" AND indicate thecapacity in*

*L)*cylinders, including 4 fully equipped spare filling outlets in-line.

- The line to be copper/brass with an on-line pressure gauge.
- Automatic change over valve connected to manifold with copper tubing.
- Safety pressure relief valve - brass construction and rated at 25% above designed distribution pressure. Discharge valve to be one-sixth larger than main supply.
- Manual spindle-type isolation valve and a non-return valve for*each* cylinder connection.
- Braided Polytetrafluoroethylene (PTFE) connectors.
- The tail-pipe cylinder connector must be compatible with cylinders, e.g. a pin index yoke connector in accordance with BS EN ISO 407:2004 for oxygen with M20 x 2 threads.
- Restraining chain for each cylinder and valve key easily accessible.

Cylinders

- All cylinders must be supplied with valve and valve guard (compatible with both filling and distribution manifolds).
- The nominal and usable capacity of oxygen gas cylinderscommonly used on manifolds are J-size at 137 bar where usable capacity (6,540/6,800 L) is given for a discharge to a gauge pressure of 7 bar.
- Cylinders to meet *** standards
- Assurance of compatibility with both cylinder filling and distribution manifolds.
- Number *(500)* cylinders of (J-size) to be included.
- 4 x oxygen cylinder trolleys capable of transporting cylinder of (J-size) must be provided.

Evacuator for cylinder filling

- The vacuum pump must be of the direct drive, oil-sealed rotary-vane type
- The vacuum pump must contain no copper alloys.
- The vacuum pump must include a check-valve to prevent any back-flow.
- The vacuum pump motor must be 380 V three-phase, 50hz

Section 4: Distribution Manifolds

4.1 General

- The installation of themanifold system should be carried out only by specialist firms registered to BS EN ISO 9001:2000 and BS EN ISO 13485:2016, with the scope of registration, appropriately defined.
- All sources of supply should be fitted with a test point comprising a weatherproof terminal unit and lockable isolating valve.
- A cylinder manifold installation comprises primary and secondary supply system.
- Total cylinder storage is usuallyprovided on the basis of a needs assessment:
    - Eachbank of the primary manifold should have sufficientcylinders for two days
    - Additional cylinders for onecomplete bank change should be held in themanifold room.
    - Sufficient additional cylinders should be held in the medical gas store to ensure continuous supply for one week.
- The operational policy document should set out the location of emergency manifolds, cylinders etc., and the action to be taken in the event of loss of the primary source of supply to ensure continuity of supply.

4.1.1 Location of and access to manifold rooms

- Cylinder gas supply systems should not be located in the same room as the PSA system and at least 50 m away from any compressor system.
- Main distribution manifolds and emergency/reserve manifolds for PSA systems should be located to take into account locations of both the cylinder storage area and the terminal units. They may be located in the same room as one another and on an external wall(s) to facilitate ventilation (see 2.3.1 Ventilation& Air Circulation/Conditioning).
- Normal commercial lorry/truck access is suitable for gas cylinder delivery vehicles, but consideration should be given to the provision of a raised level loading bay to reduce cylinder handling hazards.

- Two doors are preferable for a manifold room. One should be large enough to facilitate cylinder handling and must be on an outside wall. Exits must be free of all obstructions. Doors must open outwards. All doors must normally be locked to prevent unauthorized access, but should be provided with means of entry and exit in an emergency (for example by a push-bar arrangement on the inside).

4.1.2 Construction and layout of manifold rooms

- The manifold room will contain the manifolds as well as cylinder racks holding sufficient spare cylinders as determined by the needs assessment and Plant sizing.
- The manifold room should be designed accordingly, allowing for adequate space for cylinder handling.
- A typical automatic manifold with two duties and two stand-by cylinders are 1.8 m long and 0.6 m deep. One extra cylinder on each bank adds approximately 0.5 m to the overall length so that a 2 x 6 m manifold is approximately 4 m long.
- All medical gas manifolds may be installed in the same room. Additional floor area should be provided to accommodate separate storage racks for each gas if the facility has other gases. The racks should be designed along the lines of those on the manifolds, but the stored cylinders may be closer together. Racks should conform to ISO 32:1977.
- Internal walls and ceilings, including any internal doors of the manifold room, should be of a suitable, non-combustible, two-hour fire-resistant material as defined in BS 476-4:1970 and BS 476 Parts 20–23 (1987). Automatic fire suppression should be considered.

4.1.3 Manifold component specifications

- All copper to be of the standard BS EN 1978:1998
- All brass to be of the standard BS 2874:1986 CZ 121
- All components for oxygen use to be cleaned to aninternationally accepted procedure approved by ASTM G93 or equivalent and sealed in individual packing.
- All joints except screwed connections to be brazed with all trace of flux residue removed.

- Extreme care is to be taken when using PTFE tape on threaded joints; avoid application with any grease on hands and avoid application where overhanging pieces can become dislodged and flow into the piping.
- Pipelines for filling manifolds and oxygen distribution, as well as all gauges, valves, indicators, safety devices and testing kit,must be sourced from reputable brands; where possible, the brand/manufacturer of the offered valves must be mentioned and detailed technical specifications provided with the bid.

4.2 Primary supply system

- The primary supply is manifold provided by two banks ofequal numbers of gas cylinders, one “duty” and one “stand-by”, which are connectedto the pipeline via a control panel.
- This primary manifold is to consist of ***2 x (*# 10cylinders*)*** housing ***(*J-size*)*** cylinders.
- At each cylinder connection point:
    - Manual spindle-type isolation valve and non-return valve in copper/brass.
    - Braided PTFE connectors preferable.
    - Restraining chains for each cylinder and valve key easily accessible.
- Changeoverfrom the “duty” to the “stand-by” bank of cylindersshould be by anautomatic rotating valve at a pressure to maximize usage of cylinder contents in the duty bank.
- High- and low-side pressure gauges for each bank
- All manifolds must becapable of passing the full pipeline flow.
- Thetemperature of the gas may fall to -30°C asthe gas passes through the regulator at maximumcapacity; equipment should be designedaccordingly.
- A schematic layout for a primary supply systemis shown in (***insert facility specific schematic***).
- If changeover controldepends on an electricity supply, the design shouldbe such that failure of the electricity supply doesnot disrupt the flow of gas to the distribution system.
- Manifolds and control panels should be designedand certificated for use with 230 bar cylinders.

- The manifold headers should incorporate a renewablenon-return valve to prevent the discharge of a complete bank of cylinders in the event of “tailpipe” rupture.
- Non-metallic flexible connectors should not be used. If non-metallic materials are used, plans for sintered filter use and ignition risk minimization test results must be provided.
- Where it is necessary to use non-metallic materials, consideration should be given to the use of non-halogenated polymers in high-pressure systems (>3000 kPa/30 bar) delivering oxygen with concentrations greater than that in ambient air.

4.2.1 Pressure control

- Pressure indication should be provided, by means of minimum leak devices, to indicate pressure in each cylinder bank and in the pipeline system. High-pressure regulators should comply with BS EN ISO 10524-2:2006.
- Gauges must be marked in kPa/Bars and all gauges for the oxygen circuit must be provided with a certificate for oxygen service.
- Pressure control should maintain nominal pipeline pressure within the following limits:
    - Plant/manifold outlet pressure: 420 kPa (safety valve setting: 530 kPa)
    - Pressure switch settings (alarms): High – 500 kPa, Low – 370 kPa
    - Pressure in front of terminal units: nominal 400kPa (max. allowable drop 5%)
- Separate pressure regulating valves should be provided for each cylinder bank. The control system should be designed so that cylinders of one bank can be changed, or the pressure regulator for one bank can be overhauled, without loss of continuity of supply.
- Pressure relief valves are to be installed:
    - On each distribution pipeline downstream of the manifold line pressure regulator and upstream of the main isolation valve.
    - Between the secondary source of supply (emergency/reserve manifold) and the pipeline distribution system.
- Pressure relief valves mustbe of brass construction and be of the self-closing type, rated at 25% above designed distribution pressure.

- Discharge valve and pipe to be at least on one size larger than main supply with flow capacity at least equal to that of the pressure regulator immediately upstream of it, and be separate for each safety valve.
- This discharge pipeline should:
    - be vented to atmosphere, outside the building, in an area where the discharge of oxygen will not present a fire hazard or cause injury to personnel.
    - terminate at least 3 m clear of any door/ window that can be opened or other ventilation/air intake.
    - have its end turned downwards to prevent the ingress of dirt and moisture.
    - be placed and protected so that frost cannot form upon it (if applicable).
    - have a warning signat the discharge
    - maintainaccess to inspection.

4.2.2 Power supply interruptions

In the event of a power failure, the following scenario, as outlined in theoperational policy document, will play out (choose one that applies to specific system design):

- When the power isrestored, the original “running bank” should be online (the same bank that was in operation prior to interruption of the supply).
- Operations will default to a specific bank followinga power failure; regardless of which bank was therunning bank prior to interruption of the supply.
- The system is designed so that both banks (dutyand standby) supply gas in the event of a powerfailure.
- The system has been designed such that automatic and manual resetting to the original condition is necessary.

4.3 Secondary source supply system

- An emergency reserve manifold (ERM) system should be provided as a secondary source of supply, either for emergency use or to permit servicing or repair.
- The supply should comprise a two-bank fully automatic manifold system as described in the primary system (except for specifications given for a reserve).
- Capacity requirements for the ERM system should be set out in the operational policy document; it should be designed to provide the design flow of the primary system and have sufficient connected capacity to supply the pipeline for at least four (4) hours. When such provision would result in more than ten cylinders on each bank, the additional cylinders should be held in the manifold rooms.
- The ERM should also be installed in an appropriate manifold room(s) separate from the Plant but in the same room as primary supply.
- All cylinder valves should be permanently open so that gas is immediately available, but one of the isolating valves should be closed.
- A non-return valve and isolating valve should be installed immediately upstream of the reserve manifold connection to the pipeline distribution system.
- The supply system should go into operation automatically via this non-return valve, and the ERM isolating valve should remain open.
- The ERM must activate automatically if thepressure in the primary manifold drops below 4 bar for both banks of the primary supply system.

Section 5: Pipelines

- All copper to be of the standard BS EN 1978:1998
- All brass to be of the standard BS 2874:1986 CZ 121
- All components for oxygen use to be cleaned to aninternationally accepted procedure approved by ASTM G93 or equivalent and sealed in individual packing.
- All joints except screwed connections to be brazed with all trace of flux residue removed.
- Extreme care to be taken when using PTFE tape on threaded joints; avoid application

with any grease on hands and avoid application where overhanging pieces can become dislodged and flow into the piping.

- Pipelines for filling manifolds and oxygen distribution, as well as all gauges, valves, indicators, safety devices and testing kit,must be sourced from reputable brands; where possible, the brand/manufacturer of the offered valves must be mentioned and detailed technical specifications provided with the bid.
- First and foremost, the number of bed and ward unit should be determined.
- Flow rate calculation should be stared from the remote area (terminal unit).
- Flow rate calculation should determine as per the department (ICU, OR, RECOVERY ROOM, emergency etc.) as per HTM-02 standard. (chapter 4 oxygen table)
- Sample equation Q= 10+(n-1)6/4…… (1) where Q=flow rate, n=no of beds
- Next to gas flow rate calculation pressure drop calculation should follow in order to determine the copper pipe size. (HTM-02 appendix –G)
- Pd=(ml/n.l)*(d.f/n.f)^2…….(2) Where ml=measured length,n.l=nearest length from tableA2(HTM-02),d.f=design flow and n.f =nearest length from table A2(HTM-02)……..(HTM-02 APPENDIX G)
- Schematic flowchart drawing is necessary starting from terminal unit to the machine room including riser drawing.
- Having total pressure drop and total flow rate Plant must be select from manufacturers standard. For example, C&H (CHINA), MEDIMAX (KOREAN), theEuropeanstandard.)
- Copper pipe should very standard non-arsenical, phosphors de-oxidized.
- Copper pipe should nitrogen purge in order to remove copper oxide (a toxic gas).
- Copper pipe fittings should be too standard to regulate pressure drop and should be welded with oxygen welding system.
- Copper pipe should have a clearance about to 150mm from electric cables, steam pipe, other heat sensible materials.
- The copper pipe from each gas pipes should have clearance 150mm.
- Cutoff valves should be placed every room and shutoff valve should place every floor.
- Gas manifolds should be standard as per the manufacturers.

- Control panel is necessary on the head of every machine.
- Copper pipe standard thickness 12mm = 0.7mm

  15-28mm =0.9mm

  35-54mm =1.2mm

  76-108mm =1.5mm
- Copper support up to 15mm maximum interval between supports 1.5m.(htm-02)
- Copper support up to 22-28mm maximum interval between supports 2m
- Copper support up to 35-54mm maximum interval between supports 2.5m
- Copper support up to 54mm maximum interval between supports 3m
- Specific to (*hospital name*), piping to (*wards: theatres, ICU – intensive care unit, maternity and pediatric, other) is to be included, approximately **m from the Plant.
- The following number of outlet points/terminal units are to be provided:
  - Theatre: number (#)
  - ICU: number (#)
  - Pediatric ward: number (#)
  - Maternity ward: number (#)
  - (another ward): number (#)
- An oxygen flow meter must be installed for measuring the output of the Plant.
- Pressure in front of terminal units indicated in section 4.2.1 Pressure control

Section 6: Plant control, monitoring and indicating systems

6.1 General

- All functions andindicators should be appropriately identified.
- Control panels containing pneumatic componentsshould have vents to permit release of pressure inthe event of component failure.
- The operating system should be capable ofautomatically restarting after reinstatement of thepower supply.

- All components of the oxygen supply system shouldbe connected to the essential electrical supply. The control system should ensure that compressorsrestart in sequence to avoid overloading theessential power supply.
- Provided that the individual compressor startersare housed in a separate compartment, thesefunctions may be carried out by separate units ormay be installed in a common panel and locatedon the Plant or on the Plantroom wall.
- The central control unit must incorporate a user-friendly touch screen 4" high-definition display with clear pictograms and indicators, providing easy access to system operational information. Specifications:
  - Supply voltage: 220V, 50Hz
  - Protection degree to BS EN 60529:1992+A2:2013: IP54 or equivalent NEMA 3S.
- The hospital/building management system should not be used to control either the oxygen Plant or the manifold(s).
- There should be control, monitoring and indicating panels outside of the Plant room where someone is always present.

6.2 Plant Control and Indication Unit

- The Plantmust be controlled and monitored by a central processing unit (CPU) located in the electrical control enclosure. The CPU must include replaceable input and output modules. The CPU must:
  - Monitor the output oxygen pressure from the PSA generator unit.
  - Indicate when the Plant is in standby mode by means of a pilot light.
  - Control the timing of the valves on the PSA generator unit.
  - Control the pressure relief valve operations.

- The Plant control unit should have a separatepower supply for each compressor and vacuumpump, controlled by a separate sub-circuit. Thedesign should be such that no single componentfailure in the control unit will result in loss ofPlant output.

- The unit should allow either manual selection ofduty/standby for each of the compressors or havean automatic sequence selection with a means formanual override.
- A warning notice that complies with BS EN ISO 7010:2012+A5:2015 should be affixed which indicates thepresence of low voltage through the CPU.

6.3 Oxygen Monitoring System

- The Plant should include a calibrated paramagnetic oxygen monitoring system comprising of an oxygen analyzer, concentration indicator, flow monitor and concentration/flow recorder.
- Connections for calibration cylinders should be provided.
- The product oxygen must be monitored for purity by means of a continuous heavy duty oxygen analyzer that will automatically alarm and shutdown at purity below 90%.
- In the event of the concentration falling below 90%, the monitoring system should isolate the PSA system from the pipeline distribution system so that the ERM operates.
- An additional, independent oxygen analyzer should be provided to monitor the ERMin the case that the main system concentration falls below 93%.
- The product oxygen must be monitored for the presence of carbon monoxide and minimum pressure.
- The monitoring system must have a power control panel with a fused safety switch and a control voltage transformer for protection against voltage drops and surges.
- All the alarm signals may be conveyed by telemetry to remote points.

6.3.1 Compressor and vacuum starter units

- There should be individual starter units for eachcompressor and vacuum pump, which shouldinclude the features recommended for each respectively.
- Each compressor should have a selector switchwhich, when turned to the “on” position, allowsthe maximum and minimum pressure switches onthe receiver to control the “on”

and “off” loadingof that compressor. An alternative “auto” positionof the selector switch may allow automaticselection of the compressors.

- There should be indicators for each compressor asfollows:
  a) green “mains supply on”;
  b) green “compressor called for”, indicatingthat the motor is electricallyenergized;
  c) the pressure produced by thecompressor.

6.3.2 Molecular sieve control unit

- The molecular sieve control unit may be mountedon the molecular sieve columns or may be locatedwith the Plant control unit.
- The vacuum pump, if provided, forms part of themolecular sieve system.
- The molecular sieve control unit should containthe following:
  a) a duty selector switch;
  b) an on/auto selector switch;
  c) a system to control regeneration of the sieves inrelation to pipeline demand;
  d) oxygen concentration, dryness and pressuresensors;
- A warning notice that complies with BS EN ISO 7010:2012+A5:2015 should be affixed which indicates thepresence of low voltage through the control unit.

6.4 Plant status monitoring

- Connections should be provided that allowsmonitoring (but not control) of the Plantoperation. For example:
  - Compressor – “on”, “off”, “on-load”, “unloaded”;
  - Molecular sieves – “on” or “off”.
- These connections should be used to provide inputto the hospital energy management and buildingmanagement systems.
- A monitoring system must be provided to detectthe following:
  a) Plant faults – each compressor:
  i. Control circuit failed;

ii. Overload tripped;

iii. After-cooler temperature high;

iv. Compressor temperature high;

v. Compressor run-up time too long;

vi. Activation of other safety devices suppliedby the manufacturers;

b) Plant faults – each molecular sieve unit:

i. Control circuit failed;

ii. "Vacuum pump called for";

iii. Overload tripped;

iv. Activation of any of the safety devicessupplied by the manufacturer;

v. Oxygen concentration failure;

vi. Pressure fault;

c) Plant emergency:

i. Oxygen concentration failed at below 90%concentration;

ii. Receiver pressure 0.5 bar (gauge pressure) below the standby cut in pressure;

iii. Dryness above 67 ppm (-46°C atatmospheric pressure);

d) Pressure fault – cylinder reserve:

i. the pressure in either bank below 50% (ofnormal cylinder pressure);

e) Pressure fault – pipeline:

i. Low pipeline pressure;

ii. High pipeline pressure.

6.4.1 Plant status indicator unit

- Central status indicator panel: Warning and alarm conditions for all medical gas supply systems should be displayed on a central panel located in a position where there is acontinuous 24-hour occupation. It should have a warningnotice that complies with BS EN ISO 7010:2012+A5:2015 toindicate the presence of low voltage.
- Repeater status indicator panel:To display all or some of the information from the central alarm so that appropriate action can be taken to ensure the continuing operation of the

system(location to be determined based on facility layout). Some warning system information may be appropriate for display in specific departments, e.g. cylinder manifold status information in a porters' room, and oxygen concentration in the pharmacy department when a PSA Plant supplies the hospital pipeline installation.

- There should be indicators for each compressor toshow the following:
  a) Green "mains supply on";
  b) Yellow "control circuit failed",
  c) Yellow "overload tripped";
  d) Yellow "after-cooler temperature high";
  e) Yellow "compressor temperature high";
  f) Yellow for each individual safety deviceprovided by the manufacturers;
  g) Yellow "compressor failure".
- There should be indicators for each molecularsieve dryer system to show the following:
  a) Green "mains supply on";
  b) Yellow "oxygen concentration fault";
  c) Yellow "pressure fault";
  d) Yellow "dryness fault". (When the stand-by dryer is in operation, conditions (b) and (c) above – "control circuit failed" or "overload tripped" should be transmitted as a Plant emergency either to the alarm system.)

6.5 Manifold monitoring and indicating system

- The manifold control unit should include a green "mains supply on" indicator.
- The manifold monitoring, indicating and alarm systems should be on the essential electrical supply and perform the following:

6.5.1 Manifold monitoring

Each automatic manifold should be provided with monitoring to detect:

a) Duty bank operating;
b) Duty bank empty and stand-by bank operating;
c) Stand-by bank below 10% capacity, when the duty bank is empty;
d) Each secondary supply/ERM bank below nominal 68 bar pressure;
e) Pipeline pressure faults outside the normal range.

6.5.2 Manifold indicator unit

There should be indicators to show the following conditions:

- For each automatic manifold:
  a) A green “running” indicator for each bank. This should display when the bank is supplying gas, irrespective of the pressure;
  b) A yellow “empty” indicator for each bank when the running bank is empty and changeover has occurred;
  c) A yellow “low pressure” indicator for each bank to be illuminated after thechangeover, when the pressure in the running bank falls to the low-pressure setting;
- For secondary supply/ERM bank(s), a yellow indicator to be illuminated when the pressure in the bank falls below 68 bar (one pressure sensor for each bank);
- For the pipeline distribution system, a red “low pressure” and a red “high pressure” indicator to be illuminated when the respective conditions occur.

6.6 Warning & Alarm Systems

- The provision of a warning and alarm system as part of the overall Plant control system is essential to monitor safe and efficient operations of an oxygen Plant and/or pipeline systems for the following reasons:

a) To indicate thenormal function of the pipeline system by means of visual indicators;
b) To warn by visual and audible indications that routine replacement of cylinders or other engineering action is required;
c) To inform the user by visual and audible emergency alarms that abnormal conditions have occurred which may require urgent action by the user.

- Warning and alarm systems comprise pressure sensors, a central system providing information on all monitored functions, with repeater panels located where information is required to ensure the necessary action is taken. Area alarms should be provided to give warning to users downstream of the designated departmental area valve service units (AVSU).
- If any abnormal conditions indicated herein should be transmitted to the central alarm system.
- Where relays are used, they can be either:
    - Energized relays, which de-energize under fault conditions, with contacts having a minimum rating of 50 V DC and 50 mA; or,
    - Volt-free; normally closed contacts rated at 50 V DC and 50 mA should be provided for transmission of any abnormal conditions indicated below.
- When a warning or alarm signal occurs and the system condition subsequently reverts to normal, the corresponding visual and audible signals should automatically reset to normal.

6.6.1 Alarm signal status unit- Plant

The following indication of Plant conditions should be provided:

a) Green “normal”: *normal*
b) Yellow “Plant fault”:
“control circuit failed”, “overload tripped”, “after-cooler temperature high”, “compressor temperature high”, or “compressor failure”

c) Yellow "Plant emergency":

"control circuit failed", "overload tripped", or "compressor failure"

d) Yellow "emergency supply low": *ERM bank(s) low (<50%)*

e) Red "pipeline pressure fault": *Pressure fault*

f) Red "pipeline concentration below 93% O_2": *Oxygen concentration fault*

- The alarm signal status unit, provided as part of the control system, should be suppliedfrom all individual Plant control units, or from aseparate common supply.
- If this panel is mounted separately to the Plant indicator unit, the cablingshould be monitored for theopen/short circuit. In theevent of such a cabling fault, a red "system fault" lamp should be illuminated on the alarm signalstatus unit, together with the appropriate alarmcondition.
- The feedback from each analyzer must be monitored by the oxygen monitoring system. If an analyzer goes out of range, the control circuitry will indicate visually, audibly and/or shut down output flow depending upon which parameter is out of range. In the case of output flow shut down, the backup oxygen supply will be automatically activated.

6.6.2 Alarm signal status unit - Manifold

The following indication of manifold conditions should be provided:

a) Green "normal": *normal*;

b) Yellow "duty bank empty, stand-by running": *change cylinders*;

c) Yellow "duty bank empty, stand-by low": *changecylinders immediately*;

d) Yellow "ERM bank low": *reservelow*;

e) Red "pipeline pressure fault": *pressure fault*.

- Connections should be provided that allow monitoring of manifold alarm conditions (b) to (e) and manifold running for each "bank".
- If this panel is mounted separately from the manifold control unit, the cabling should be monitored for theopen/short circuit. In the event of such a cable fault, a red "system

fault" lamp should be illuminated on the alarm signal status unit, together with the appropriate alarm condition.

6.6.3 Visual signals

- All visual signal panels should be permanently labeled according to their function, including clear identification of the areas, rooms or departments served.
- There should be two separately energized light sources for each signal, arranged so that the failure of one source does not affect the other.

6.6.4 Audible signals

All audible signal tones should be modulated equally at a rate of 4 Hz ±10% between two tones: 440 Hz ±10% and 880 Hz ±10%.

6.6.5 Temporary muting

- Means must be provided on each panel for the user to temporarily mute the audible signal. The signal must resound after a nominal 15-minute period if the fault condition still exists.
- Operation of mute on the central panel should be accompanied by achange from flashing to steady illumination of the corresponding visual indicator on the central and any repeater panels.
- Operation of mute on an area alarm or repeater panels should not be accompanied by a change from flashing to steady illumination.

6.6.6 Continuous muting

An internally-mounted switch should be provided to allow for continuous muting during periods of maintenance. When the system condition returns to normal, the continuous muting should automatically reset to normal operation. When the continuous muting is in operation on any

alarm condition, it should not prevent the operation of the audible signal on other alarm conditions when a fault condition arises.

Section 7: Electrical for controls

7.1 General

- All electrical wiring should be in accordance with BS 7671 or Ethiopian Electric Light Power Authority (EELPA).
- The electrical control enclosure must have an hour meter showing system hours of operation and indicator lights giving thestatus of the system operation.
- The mains electricity supply should be derived from the essential power supply (that is, must be on the emergency system).
- The machine working voltage must be 380AC ±15 Volts with 3 phase, and five wire system.
- Phase sequence controller
- At least 3 step down transformer at the same output for reserve.
- Distribution box with lockable key.

Operating Environment

- The system offered must be designed to store and be operated normally under the condition of 10-45 0c, humidity <95% and with altitude of to the maximum 2500 meter above sea level

7.2 System integrity

- If extra low voltage (ELV), max. 50 V is superimposed on the signal or communication circuit (e.g. by cross-connection), the system design should ensure that a fault is indicated and any damage to the system is limited to replaceable panel components.

- The performance of the system should not be compromised by the use of multi-core cabling that carries ELV and communication signals in adjacent cores.
- The system should be designed to reject spurious radio frequency or mains noise typically arising in hospitals (e.g. diathermy equipment, current spikes caused by Plant start-up, etc.)
- Each panel should be provided with a means to test all visual and audible signals on that panel. The power supply should be capable of sustaining all indicators and audible signals.

7.2.1 Safety extra low voltage/functional extra low voltage power supply

- Panel power may be designed either as a *safety* ELV system or as a *functional* ELV system (BS 7671).
- The ELV power supply may be housed either in the alarm panels or in a separate metal enclosure.
- The power supply should be rated for the full load of the panel, with visual and auditory signals on all normal and alarm conditions.

7.3 Warning and alarm system faults

A flashing red visual indicator and an audible signal should operate on all panels when any of the following conditions occur:

7.3.1 Line fault

The system should monitor the integrity of the lines between the initiating devices and the panel or transmitter units. The “alarm system fault” condition should be indicated on loss of integrity, e.g. open or short circuits, together with visual alarm indicator(s) associated with the faulty wiring.

7.3.2 Communication/wiring fault

The system should indicate an alarm system fault in the event of loss of data transmission between panels and transmitters.

7.3.3 Mains power failure

Failure of mains power should be shown by a flashing red indicator and an audible signal, which should be powered by an internal battery. The audible signal may be muted and not automatically reinstate as required under normal power supply, but the visual indicator should continue to flash until either the fault has been rectified or the battery has discharged.

7.3.4 Standby battery

A battery should be provided with sufficient capacity to power the visual and audible "alarm system fault" signal for a minimum period of four hours. The battery should be sealed and exchangeable, and should automatically recharge within 72 hours.

Standards and Safety Requirements

European Norm (EN), International Standards Organization(ISO), American Society for Testing and Materials(ASTM), American Society of Mechanical Engineers(ASME), European Committee of Manufacturers of Electrical Machines & Power Electronics(CEMEP) and Medical devices approval certificate must be provided.

Section 8: Validation & Verification

The objective of validation and verification is to ensure that all the necessary safety and performance requirements of the Plant will be met. Validation and verification procedures, including testing and commissioning procedures, will be required for new installations.

- The scope of work will dictate the specific program required.

- All production and supply systems and their major components should have compliance certificates as specified throughout this document.
- Only suppliers who are registered to BS EN ISO 9001:2000 and BS EN ISO 13485:2016, with their scope of registration defined to include commissioning, should undertake engineering validation and verification (testing), though it is not necessary for appropriately trained and appointed hospital-based Quality Controllers.

8.1 Prior to shipment

- The Plantmust be complete in all respects. Before contract signing and Plant shipment, a technical representative on behalf of the *owner*should visit the supplier's factoryto carry out due diligence by means of a Factory Acceptance Test (FAT). During the FAT:
    - Vital equipment/accessories like electrical motor, compressors, control panel and other items will also be inspected to confirm quality.
    - The supplier must operate the Plant at the desired performance and efficiency for at least 72 hrs.continuously at full load parameters. Log sheets must be filled with the following parameters: Energy per meter cube of oxygen, Capacity per hour, pressure, purity of gas etc. These must be measured and confirmed.
    - Demonstrate performance at extremes of power quality as per specification.
- Any modifications found necessary during the FAT will have to be carried out by the supplier at no additional cost.
- Four (4) copies of the testing documents (tests and results) and inspection certificates for all components will be furnished along with the dispatch of thePlant.
- The supplier must furnish a Gantt/activity bar chart, civil engineering drawings, foundation design details, loading details, layout plan, electrical plans, etc. immediately after signing the contract.
- The Plant, with all its accessories, must reach the site in one lot. The Plantmust be supplied with all the foundation bolts, leveling, aligning, anchoring and other material required for complete installation.

8.2 After installation in-country

- The Plant is to be completed in all respects before validation and verification begin.
- Activities, manpower, material, instruments etc., required for satisfactory installation, testing,andcommissioning of the Plantsmust be the responsibility of the supplier.
- The supplier should provide instrumentation for the functional tests. Calibration certificates should be available withthese instruments. The Supplier must also furnish the quality control personnel (Quality Controller) with a set of all required instruments/devices for necessary ongoingcalibrating and testing.
- In the case of engineering tests, this must include all cylinders of test gas together with "open" bore non-interchangeable screw thread (NIST) connector probes, pressure-measuring equipment,and gas specificity/ flow pressure testing device(s), and metered leaks test equipment.
- All relevant tests after installation should be carried out by the supplier alongside the facility Quality Controller, and witnessed by ***. All test results will be recorded and become part of the permanent records for the Plant.
- Successful completion of the commissioning tests indicates the end of the installation contract.
- Systems that are not to be taken immediately into use should be filled with medical air and maintained at operating pressure. In this circumstance, the particulate contamination and odor/taste tests may be carried out before purging and filling with the working gas (Responsibility for the system during this period needs to be clearly defined in the contract).

8.3 Program of tests and checks

The program of tests required for validation and verification of new installations, shown in a testing and commissioning decision tree in Annex 2, is divided into 3 steps which are to be carried out in the order given by the supplier in the presence of the Quality Controller for

training purposes: pipeline carcass, pipeline system, and quality assurance / quality control. (More details in Section 9: Training of Plant operators and Hospital staff.)

8.3.1 General

- When testing/purging is carried out on systems serving an operational hospital, it is essential to ensure that under no circumstances will critical medical activities be disrupted. If medical gases are already being used in the facility, continuity inflows are not to be impaired in operational areas.
- Clean, oil-free cylinders of dry medical air are normally used as the gas for purging and testing of oxygen systems in order to prevent the possibility of contamination with oil. Special connectors will be needed to introduce test gas into the pipeline (if needed). These must be of distinctive construction and permanently labeled with their function and the supplier's name. The location of special connectors must be recorded and should be subject to routine inspection under a planned preventative maintenance (PPM) system as outlined in the operational policy document. They should be removed from thesite when work is complete and the supplier should record their removal.
- Where the use of cylinders will be impracticable because of scale, total system performance tests can be carried out by using the medical air compressor system (if available), provided that the quality tests have been satisfactorily carried out to demonstrate that the medical air quality criteria have been met and that the air supply Plant is continuously monitored for moisture during the test.
- For total system pressure tests on oxygen, the system under test must be physically isolated from the source of supply (for example by the use of spades).
- An on-line dew-point meter should be fitted to the Plant or pipeline system.
- A compressor system can also be used for the single point performance testsas well as for initial purging and particulate testing of these systems.
- When employing compressors for this type of test, it is important that system demand does not exceed the maximum flow capacity of the dryers, otherwise wet air will result. It

is suggested that the total flow required by the system under test should not be more than 75% of the flow capacity of the dryers.

- It is important not to introduce such a compressor after identity checks have taken place.
- Special care will be required when carrying out quality control checks, as some synthetic oils cannot be detected using portable equipment.
- New terminal units are supplied with “Do not use” labels which are to remain in place until the final identity and quality tests have been completed. They are then removed by the Authorized Person.
- In the case of existing systems, “Do not use” labels should be affixed to all terminal units within the section being modified.
- The results of all tests must form part of the permanent records of the hospital and should show details of the services and areas tested. All signatories are entitled to copies of the test forms. The procedure for filing and retaining these forms should be included in the operational policy document.
- All errors found during testing must be rectified, and the relevant systems must be re-tested as appropriate before the records are signed.
- The Quality Controller will be trained by the supplier in all equipment for gas quality and identity testing prior to handover of equipment, including regular servicing and calibration of said equipment. On-site pre- and post-testing calibration of equipment against an appropriate standard will be performed at the discretion of the Quality Controller.
- The Quality Controller will be responsible for supplying all forms as per FMoH standard.
- In a completely new installation, under no circumstances must medical equipment be moved into rooms until validation and verification tests have been satisfactorily completed.

8.3.2 Pipeline carcass

The following tests must be carried out after installation of the pipeline carcass but before concealment:

a) Visual check of pipeline labeling, markingand support;
b) Leakage test;
c) Tests for cross-connection;
d) Valve tests for closure, zoning,and leakage. To note, testing for leakage is normally carried out in two stages: the first to the pipeline carcass, the second to the completed distribution system as part of the pipeline system test, which will include terminal units and medical supply units as appropriate.

8.3.3 Pipeline system

The following testing and commissioning of the complete pipeline system for safety, performance and particulate contamination using test gas must be carried out after completing theinstallation of the pipeline system (with terminal units installed):

a) Tests for leakage on the pipeline system;
b) Tests of AVSUs for closure, correct service,and control of the terminal units in the zone: checks for correct labeling of AVSUs for zone reference and identity of terminal units controlled and flow direction indication;
c) Tests of line valve assemblies for closure and identification;
d) Tests for cross-connection, flow, pressure drop, mechanical function and correct identity of the terminal units; checks for correct labeling and association with AVSUs (only required for separate circuits for thesame service in one area, e.g. dual/split circuits);
e) Tests for mechanical function and identity of NIST connectors;
f) Performance tests of the pipeline system;
g) Checks of safety valve certification;
h) Tests of warning system;
i) Tests for particulate contamination/ odor/taste: these may be carried out immediately after installation using medical air[1], or after purging and filling with oxygen. It is intended that the Quality Controller is handed over a system that is purged clear of gross

[1]to establish that the pipeline has been constructed correctly and is not contaminated.

particulate contamination before being filled with the working gases. However, it is accepted that this may not always be possible.

8.3.4 Quality Assurance / Quality Control

Before use, the following tests must be carried out after purging and filling with the working gas for the purpose of gas identity and quality prior to use for patient care:

a) Tests for particulate contamination;
b) Tests for gas identity;
c) Tests for gas quality.

Flow & pressure:

- Test flow, liters per min (lpm), measured at standard temperature and pressure at terminal unit outlet:
  - 100 lpm (operating &anesthesia rooms),
  - 10 lpm (all other terminal units), though typical flow 5-6 lpm
- Minimum pressure at design flow measured on the test gauge: 370 kPa
- Nominal pipeline distribution pressure: 400 kPa in case nebulizer or other respiratory equipment is used.
- Plant pressure: 420-500kPa

Oxygen quality

Table 4 Components and standards for oxygen quality

Component	Standard	
	European Pharmacopoeia (Ph. Eur.) Oxygen 93	USP Oxygen 93
Oxygen v/v%	93 ±3%	> 90% < 96%
Oil	0.1 mg/m^3	*not specified
Carbon Monoxide	5 ppm	5 ppm
Carbon dioxide	300 ppm	300 ppm

Water	≤ 67 ppm vpm (≤0.05 mg/L, atmospheric dew point of –46 °C)	*not specified
NO & NO2	≤ 2 ppm v/v	*not specified
SO2	≤ 1 ppm v/v	*not specified
Odor/taste	None	*not specified

8.3.5 Labelling, marking and signage:

A visual check must be made on each pipeline system to ensure that the pipelines are labeled in accordance with the contract specification and that the terminal unit base blocks are marked in accordance with BS EN ISO 9170-1:2008.

Section 9: Training of Plant operators and Hospital staff

- Training of the Plant Operators must be carried out in "Country" for at least 2 weeks at the ("Plant name") Plant in ("hospital name"). Each Hospital must have at least two (2) dedicated Plant Operators.
- Training shall be offered for engineers/ technicians to ensure transfer of technology and also future maintenance, operation,and Calibration.
- Onsite training during installation in the hospital for users and technicians
- The Plant operators must be issued certificates after completing the training indicating the trained persons as certified Plantoperators. ***The Plant operators must be Nationals recruited in conjunction with the Hospital Administration with a minimum qualification of ***Biomedical/Electrical/Mechanical technician and an experienced computer user.***
- The training for (*operators and supervisors*)must cover all aspects of standard operations, basic maintenance (mechanical, electrical and electronics) and related safety procedures.
- Ongoing operations, maintenance and testing schedules to be clearly defined and included in the user and maintenance manual.
- Oxygen Plant operators/technical staff will be trained in collecting Plant performance data using standardized technical data sheets designed to evaluate the performance of the Plant and accessories after the Plant has started operating.

- The Supplier's technical staff will be available to provide required operational support for at least 2 years and thereafter scheduled service/maintenance, as per agreement.

Section 10: Documentation required

The supplier of the Plantmust furnish four (4) complete sets of the following documents in English:

1. General layout plan (schematics) for thecompletePlant, including cylinder filling ramp and distribution manifold, with dimensional details and floor space requirements.
2. As built detailed Civil and Electro-Mechanical Engineering drawings with foundation details, loading details,and dimensional details.
3. All documentation from the FAT and post-installation testing.
4. User and maintenance manuals, including all details and schedules of necessary works.

Section 11: Guarantees/Warranty

The Manufacturermust provide Guarantee for all equipment and Plant with respect to design, material, construction, performance, and operation, including a guarantee against any manufacturing defects for a period of not less than 24 months from thedate of commissioning & handing over. Included in the costing, the manufacturer must provide all after-sales service and free replacement of defective parts during the guarantee period. An additional extended warranty of 8 years must be provided by the Supplier as part of a comprehensive 10-year service/maintenance contract that will be signed with the supply and installation contract.

Section 12: Maintenance

A comprehensive maintenance/service agreement for the Plant and auxiliary equipment for a period of ten (10) years after commissioning and handover should be considered to include the following:

- Maintenance will consist of inspection, corrective and preventive maintenance at regular intervals indicated by themanufacturer and outlined in the user and maintenance manual.
- All equipment and accessories of the oxygen Plant will be regularly inspected, serviced and repaired by the supplier, including replacement of parts.
- An annualized operation and maintenance cost estimate for ten (10) years will be provided.
- A costed list of fast moving spare parts projected for consumption for ten (10) yearswill be provided.
- The Supplier's Engineers will undertake at least two inspection visits to the Plant during the first year after commissioning and at least one visit per year thereafter at no additional cost to the client.
- A complete toolbox containing a set of tools, calibration and testing equipment must be supplied with each Plant.
- User and maintenance manuals will be supplied with each Plant.
- The Supplier and Client must conclude an operation, service and management agreement for 10 years renewable.

Annex 1 – Standards Referenced

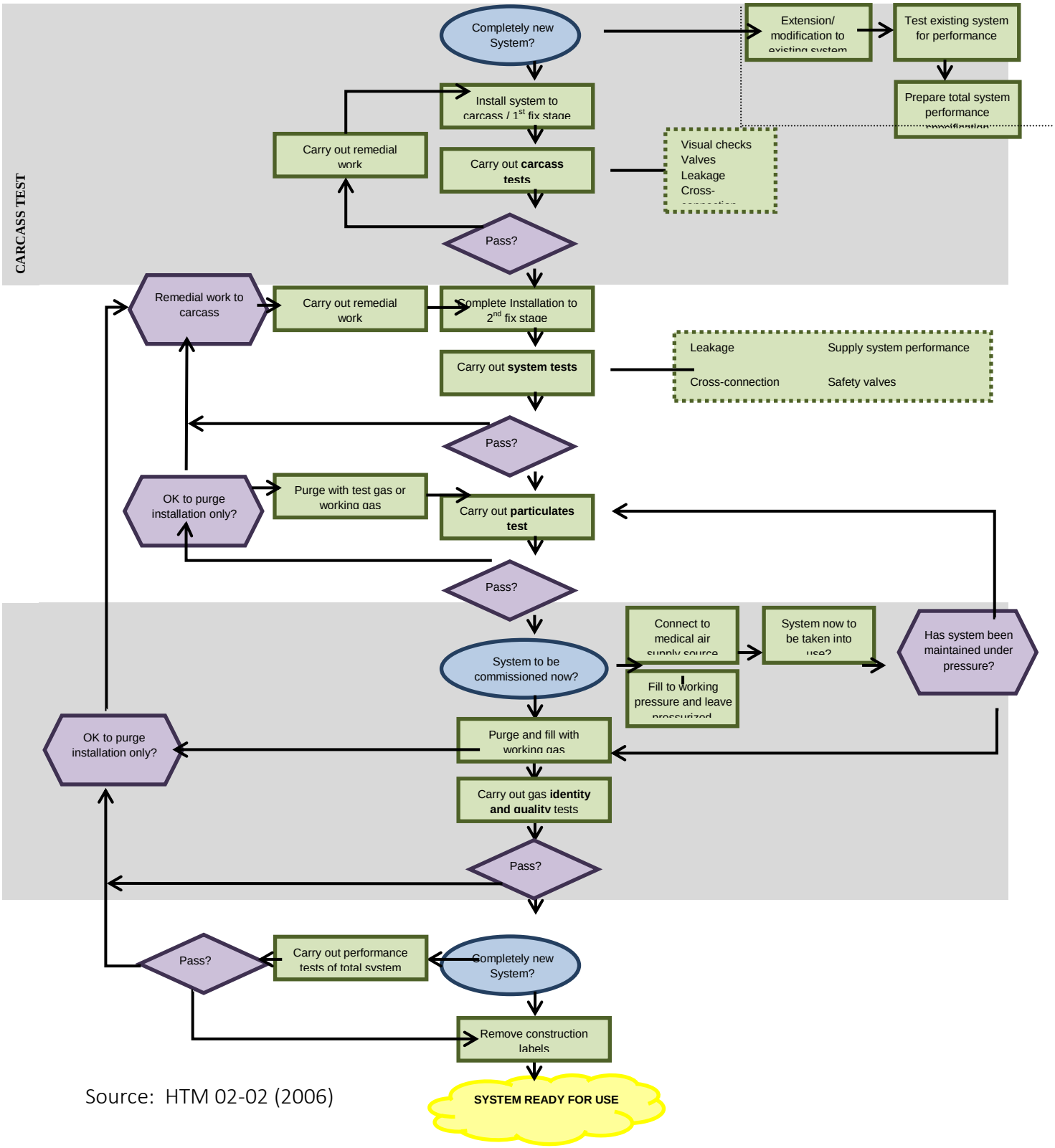
Referenced Standard	Description
BS EN 737-3:2000	Medical gas pipeline systems. Pipelines for compressed medical gases and vacuum
ISO 7396-1:2016	Medical gas pipeline systems -- Part 1: Pipelines for compressed medical gases and vacuum
BS EN 60529:1992+A2:2013	Degrees of protection provided by enclosures (IP code)
BS ISO 9001:2001/ BS EN ISO 13485:2016	Quality management systems Medical devices -- Quality management systems -- Requirements for regulatory purposes
CE mark	ConformitéEuropéenne (European conformity)
ASME VIII code, directive 97/23/EC	Boiler pressure and vessel code
BS ISO 5011:2000	Inlet air cleaning equipment for internal combustion engines and compressors -- Performance testing
ISO 8573-1:2010 Class 1, clause 1-2-1, 1-4-1	Compressed air -- Part 1: Contaminants and purity classes
ASTM G93	Standard Practice for Cleaning Methods and Cleanliness Levels for Material and Equipment Used in Oxygen-Enriched Environment
BS 476-4:1970 parts 20-23 (1987)	Fire tests on building materials and structures. Non-combustibility test for materials
ISO 32: 1977	Gas cylinders for medical use -- Marking for identification of content
BS EN 1978:1998	Copper and copper alloys. Copper cathodes
BS 2874:1986 CZ 21	Specification for copper and copper alloy rods and sections (other than forging stock)
BS EN ISO 407:2004	Small medical gas cylinders -- Pin-index yoke-type valve connections
BS EN ISO 15001:2010	Anesthetic and respiratory equipment. Compatibility with oxygen
BS EN ISO 10524-2:2006	Pressure regulators for use with medical gases. Manifold and line pressure regulators
BS EN ISO 7010:2012+A5:2015	Graphical symbols. Safety colors and safety signs. Registered safety signs
BS 7671	Requirements for Electrical Installations.
BS EN ISO 9170-1:2008	Terminal units for medical gas pipeline systems. Terminal units for use with compressed medical gases and vacuum

Note: BS : British Standard, EN: European Norm, ISO: International Standards Organization, ASTM: American Society for Testing and Materials, ASME: American Society of Mechanical Engineers, CEMEP: European Committee of Manufacturers of Electrical Machines & Power Electronics

Further, best practice guidance was heeded by using the following references

- Health Technical Memorandum 02-01: Medical Gas Pipeline Systems - Part A Design, Installation, Validation and Verification, published by the Department of Health (UK) in 2006.

Annex 2 - Testing and commissioning decision tree



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